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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,886	09/19/2003	Andrew H. Segal	85849DIV5(211111)	6806

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	PAPER NUMBER
1648	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/666,886	SEGAL ET AL.
	Examiner	Art Unit
	BENJAMIN P. BLUMEL	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 and 5-11 are examined on the merits. Claim 4 remains withdrawn as it is drawn to a non-elected species.

Response to Arguments

Applicant's arguments filed 6/3/2011 have been fully considered but they are not persuasive. See responses below.

Double Patenting

In response to the double patenting rejections set forth in the previous office action, and restated below, Applicant submits that upon notification of otherwise allowable subject matter in the instant case, Applicants will address the double patenting rejections.

Applicant's intention is noted. However, until the rejections are properly addressed, with the submission of a terminal disclaimer, all double patenting rejections are maintained for the reason(s) set forth in the record.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.

Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(Prior Rejection Maintained) Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/666833.

Applicants state that upon notification of allowable subject matter, they will address the double patenting rejection. Therefore, the rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 112

(New Rejection Necessitated by Amendments) Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites, "…said cell divides at a rate that is less than about 50% of the rate of division of corresponding cells which are not treated to prevent division."

Therefore, the examiner is interpreting claim 8 to actually state that the cells employed in the composition have been treated to prevent division. Based on this interpretation, it is unclear how a cell that has been treated to prevent division can still divide as implied by the claim [i.e., "…cell divides at a rate that is less than about 50%..."].

Claim Rejections - 35 USC § 103

(New Rejection) Claims 1-3 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoo (US Pat. 5,891,432) and Tykocinski and Zheng (US PGPub 2003/0206917).

The claims are directed to a composition comprising a virus or cell, and a fusion polypeptide comprising i) a first amino acid sequence that comprises a cell-surface binding moiety and ii) a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein the virus or cell and the fusion polypeptide are bounded via a lipid on said virus or said cell, and unbounded together. Claim 2, which depends on claim 1, limits the second amino acid sequence to a ligand for a cytokine receptor, which is limited to GM- CSF by claim 3. Claim 5, which depends on claim 1, requires the cell to be a tumor cell, a bacterial cell, a fungal cell, a cell of a parasite, a mammalian cell or an insect cell. Claim 6, which depends on claim 5, requires the cell to be a pathogenic cell. Claim 7, which depends on claim 5, requires the cell to be an attenuated cell. Claim 8, which depends on claim 1, requires the cell to be unable to divide. Claim 9, which depends on claim 1, requires the leukocyte to be an antigen presenting cell, which is specified as a professional antigen presenting cell by claim 10 and dendritic cell by claim 11.

For purposes of examination, one example of a cell-surface binding moiety is that of glycosyl phosphatidylinositol (GPI) [see paragraph 20 of instant specification].

Hoo teaches a composition. [Claims 13-24, in particular.] The composition of Hoo comprises a cell and a fusion polypeptide. [Claims 1-12, in particular.] In the composition of Hoo, the antigen and the fusion polypeptide are bounded and unbounded together. [Claim 1 and claim 12, in particular.] The antigen that Hoo teaches includes a virus, a bacterial cell, fungal cell, a cell of a parasite, a mammalian cell, pathogenic and attenuated antigens, and a cell that is substantially unable to divide. [Lines 35-45, column 10, and columns 9-18, in particular.]

The first amino acid sequence in the fusion polypeptide of Hoo comprises the sequence to a membrane attachment domain, a cell-surface binding moiety. The second amino acid sequence in the fusion polypeptide of Hoo comprises the sequence of a ligand for a cell surface polypeptide of a leukocyte. Specifically, the ligand for a cell surface polypeptide of a leukocyte is a ligand for a cytokine receptor. In particular, the ligand for a cytokine receptor that Hoo et al. teaches is GM-CSF. [Example I, column 22, in particular.] The ligand for a cell surface polypeptide used by Hoo is a ligand for a ligand for a cell surface polypeptide of a leukocyte, wherein the leukocyte is dendritic cells, which is a professional antigen presenting cell. [Columns 1-2, in particular.] In the instant case, the composition of Hoo is the same as the claimed invention. However, Hoo does not teach the binding of the fusion polypeptide via a lipid on the virus or the cell through a cell-surface binding moiety.

Tykocinski and Zheng teach the generation of fusion proteins based on GPI and a cytokine. One specific example of a cytokine is GM-CSF (see paragraph 68), which is fused with GPI. The use of GPI permits the stable fusion (immobilization) of the fusion protein to the cell membrane (see paragraph 65) as GPI incorporates into the lipid bilayer. Tykocinski and Zheng also teach that cells coated with fusion proteins that possess a portion of a protein with trans-signaling function can be administered in order to induce immune responses by interacting with other cells via the trans-signaling portion of the fusion protein (see paragraphs 54-55).

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Hoo in order to use a lipid of a virus or cell to bind a fusion polypeptide. One would have been motivated to do so, given the suggestion by Hoo that the cell-binding moieties be used to associate a fusion polypeptide with a membrane of a cell or virus. There would have been a reasonable expectation of success, given the knowledge that GPI, a cell-surface binding moiety can be fused to GM-CSF and that GPI as part of a fusion protein can be used to coat a cell with the fusion protein by stably1 associating with the lipid membrane of the host cell, as taught by Tykocinski and Zheng. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to arguments:

Applicants argue that Hoo does not teach the binding of lipid on a virus or cell (such as a leukocyte) with a cell-surface binding moiety, which is part of a fusion protein. Applicants also argue that claims 1 and 12 as cited by the Examiner in support of the

instant invention do not establish that unbound fusion proteins were part of the cellular composition that does contain fused proteins with GM-CSF.

In response to the reference only to claims 1 and 12, the Examiner also referred to claims 2-11, 13-24, columns 1, 2 and 9-18; and Example 1 in the previous Office action.

It is acknowledged that Hoo do not specifically state that a lipid is the target of their cell-surface binding moieties. However, Tykocinski and Zheng teach the generation of a fusion protein with a GPI fused to GM-CSF and the use of GPI to immobilize fusion proteins to the lipid membrane of the cell. Therefore, the instant invention is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made in view of the combined teachings of Hoo et al. and Tykocinski and Zheng. More specifically, since Hoo et al. teach the administration of cells with immobilized GM-CSF and that they do not teach washing these cells prior to administration, unbound GM-CSF was also present in the composition that is administered to the host; and Tykocinski and Zheng teach the use of a cell-surface binding moiety of GPI fused to a second protein to coat cells, one of ordinary skill in the art would have a reasonable expectation of success at generating the claimed composition.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/
Primary Examiner, Art Unit 1648